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October 14, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Ariva smokeless tobacco. Docket No. 02P-0207

Dear Sir or Madam:

The Society for Research on Nicotine and Tobacco ('SRNT' or 'Society') wrote to the FDA on April 23rd this year petitioning the FDA to regulate Ariva tobacco lozenges. The Society now wishes to respond to the letter from David Rosen of McDermott, Will & Emery on behalf of Star Scientific ("Star") on June 13, 2002 which challenged our initial petition.

We reject the argument of Star that the Society for Research on Nicotine and Tobacco is straying from its stated mission in providing advice to the FDA. Our stated goals include: "to provide the means by which various legislative, governmental, regulatory, and other public agencies and the ethical drug industry can obtain expert advice and consultation on critical issues concerning tobacco use, nicotine dependence, and the therapeutic uses of nicotine."

The Society is a pluralistic body with members holding many perspectives on interpretation of the scientific evidence, ethical and regulatory issues surrounding tobacco. However, our membership shares a broad consensus that all tobacco and nicotine products should be regulated under a coherent system in which public health and consumer protection are the prime goals. The Society has long supported FDA jurisdiction over all tobacco products and the equivalent in other jurisdictions outside the United States. This was a point we made in the original petition. At present, the most serious dangers to public health arise from products that the Supreme Court has ruled to be outside FDA jurisdiction, cigarettes. In particular, 'light' cigarettes are a serious risk to public health because they combine the implicit claim of a health benefit with no meaningful reduction in risk.

The Society therefore has a broad consensus in its call for regulation of tobacco and nicotine products. However, there are differing views on the implications of applying regulatory supervision to only a subset of the tobacco and nicotine products. For some, partial regulation extends the regulatory control in the market and represents progress towards the aim of full regulation. For others, partial regulation amounts to an arbitrary distortion that favours the unregulated forms of tobacco at the expense of products that are less hazardous than products that are not regulated.

02P-0207

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It was not our intention to single out Ariva for special regulatory scrutiny. Our original petition stated that we also submitted similar petitions on Omni and Advance cigarettes and Nicotine water.

The Society believes that consumers should expect health or therapeutic claims made for tobacco or nicotine products to be accurate, proportionate and not misleading. When the health consequences are potentially so serious an independent regulator should validate such claims. However, what constitutes a therapeutic claim and what would be an adequate level of validation are matters of legitimate debate between experts.

The Society would like to clarify the comparison made between low-tar/low-nicotine and Ariva in the petition of April 23, 2002. Low-tar/low-nicotine cigarettes branded as 'lights' or 'mild' have powerful implicit health claims but offer no meaningful health benefits compared to smoking regular cigarettes, and thereby provide the smoker with false reassurance and a rationalisation for continuing to smoke.

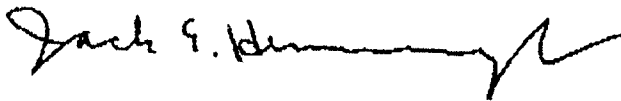
When assessing the harm caused by smokeless tobacco, several considerations are necessary to assess the overall harm, including: the relative risks caused by smoking and smokeless for a given quantity of tobacco consumption; whether smokeless tobacco is used concurrently alongside smoking; and whether, similar to light cigarettes, smokeless tobacco use reduces the propensity to quit smoking or, aids smoking cessation and ultimately cessation from tobacco use.

We hope this further response is a useful elaboration of the position of the Society with respect to the complex and controversial issues surrounding regulation of tobacco products.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Harry A. Lando".

Harry A. Lando, Ph.D.
SRNT President

A handwritten signature in black ink, appearing to read "Jack E. Henningfield".

Jack E. Henningfield, Ph.D.
Chair, SRNT Policy Committee

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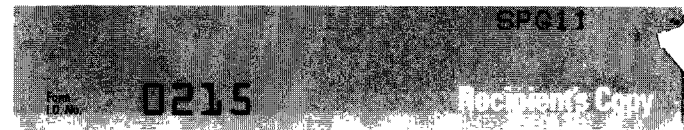
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